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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/844,517 | 04/27/2001 | Erich Hoffmann | 2427/1G772-US1 | 9063 |
| 29311 | 7590 | 05/05/2004 | EXAMINER | |
| DARBY & DARBY | | | HILL, MYRON G | |
| P.O. BOX 5257 | | | ART UNIT | |
| NEW YORK, NY 10150-5257 | | | PAPER NUMBER | |
| | | | 1648 | |

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/844,517

Applicant(s)

HOFFMANN, ERICH

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2- 17 19- 29, and 45 is/are pending in the application.
- 4a) Of the above claim(s) 2-14, 33- 38, 40, and 41- 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 15- 17, 19- 30, 32, 39, 44, and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the paper filed 12 January 2004.

Claims 2-14, 33- 38, 40, and 41- 43 remain withdrawn from further consideration.

Claims 15- 17, 19- 30, 32, 39, 44, and 45 are under consideration.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 15- 32, 39, 44, and 45 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for production of influenza viruses, does not reasonably provide enablement for the full range of negative stranded viruses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims are drawn to a minimum plasmid rescue system for any segmented negative stranded virus.

The claims were amended to recite influenza viruses and not the whole range of negative stranded viruses.

Claim Rejections - 35 USC § 102

Claims 15- 32, and 39 are rejected under 35 U.S.C. 102(a) as being anticipated by Hoffmann et al.

Applicant has filed an *In re Katz* type declaration that has been considered and the reference is no longer available as prior art.

Rejections Maintained

Claim Rejections - 35 USC § 112

Claims 29- 32 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant argues that the claims are products.

Applicant's arguments have been fully considered and found persuasive in part.

Claims 29- 32 and 39 are drawn to methods which depend from plasmids and host cells that contain the plasmids. They contain no active method steps that result in the production of infectious virus. Applicant does not address this issue except to say the claims are methods. It is suggested that the claims be rewritten to be proper dependent product claims and recite an intended use of a product.

Claim Rejections - 35 USC § 103

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Claims 15- 17, 19- 30, 32, 39, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffmann (Dissertation in translation, 1997, from IDS) and Neumann *et al.* (PNAS, 1999 in IDS).

The claims have been amended and are drawn to a composition comprising a set of plasmids each with two special promoters and each containing one genomic segment from influenza virus.

Applicant argues that there is no suggestion to combine or suggestion to produce a set of ambisense plasmids, that Pekosz *et al.* and Neumann *et al.* teach using more plasmids to obtain higher virus titer, that it is known in the art and Neumann *et al.* disclose certain amounts of viral protein are critical for production of virus, that Hoffmann *et al.* show that it is not routine optimization to use one two promoter plasmid and that publication shows that it not obvious in view of the cited art. Lastly, Applicant argues commercial success.

Applicant's arguments have been fully considered and not found persuasive.

Neumann's increased number of plasmids are needed to express additional viral proteins to increase virus yield from transfection. One of ordinary skill in the art at the time of invention would know that the additional plasmids code for additional proteins. The functional elements of the promoters used by Neumann are POLII to make mRNA and POLI to drive expression of genomic RNA on different plasmids.

Hoffmann teaches a plasmid that contains both promoters, POLI and POLII.

Pekosz teaches as is known in the art the complexity of transfection of up to 17 plasmids and the benefit of no helper virus. This would lead one of skill in the art to

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desire a helper free system that had fewer plasmids but the efficiency of the Neumann 17 plasmid result. The level of skill in the art is high as evidenced by the publications cited by Applicant. Hoffmann provides an answer to this problem by providing one plasmid that can act as both mRNA and genomic RNA. One of ordinary skill in the art would see this would result in a reduction in the number of plasmids that would be required to transfect in the system of Neumann *et al.*

Applicant argues that levels of protein expression are critical for virus production. This element is not found in the claims. This aspect would constitute a critical step in a method but not to a product claim.

Applicant argues that Hoffmann *et al.* shows that it is not routine and that the instant invention was not obvious over the cited art. The referenced art shows that there are not enablement issues with using the special plasmid. The Office cannot determine what was known or done by Hoffmann *et al.* from the referenced paper. The status of the journal and peer review of submitted papers are not determined by the Office.

The commercial success is not demonstrated by licensing or projected commercial success. Commercial success requires at least success in the marketplace, a nexus between success and the marketplace, and success is based on inventive aspects not just marketing. While long felt need and faster generation of viruses for use in vaccines may be a desirable property, as noted in Webby and Webster, there has been no showing of commercial success with specific dangerous or modified viruses. The scope of most of the concerns in the article is outside the scope of the claims.

The claims are drawn to a set of plasmids which contain influenza genomic segments as inserts.

Knowing Neumann *et al.* generated infectious influenza virus by a plasmid based system and the benefit of adding more protein expressing plasmids to the transfection and knowing that multi-plasmid transfections are complex, one of ordinary skill in the art at the time of invention would be motivated to use the plasmid of Hoffmann to reduce the number of plasmids required to transfect and save time in cloning with the expectation of success because the promoter elements used by Hoffman are the same as used by Neumann *et al.*

Thus, for the reasons above and as stated in the previous Office Action, the claims are unpatentable over Hoffmann and Neumann *et al.*

Claim Rejections - 35 USC § 103

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffmann and Neumann as applied to claims 15- 17, 19- 30, 32, 39, and 44 above, and further in view of Pleschka.

This rejection was not specifically addressed except to the part applying to Hoffmann and Neumann as applied to claims 15- 17, 19- 30, 32, 39, and 44 above.

Hoffmann and Neumann were addressed above and the rejection of record remains.

Conclusion

No claim is allowed.


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

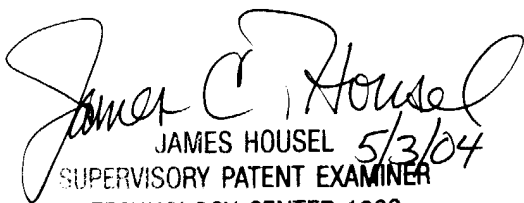
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Myron G. Hill
Patent Examiner
May 3, 2004


JAMES HOUSEL 5/3/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600